K052874

510(k) Summary

FEB - 5 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR § 807.93

Submitter:	Biomet Trauma 100 Interpace Parkway Parsippany, NJ 07054
Establishment Registration Number:	2242816
Contact:	Debra L. Bing Director Regulatory Affairs Biomet Trauma 100 Interpace Parkway Parsippany, NJ 070654 Tel.: 973-299-9300 Fax: 973-257-0232 E-mail: debra.bing@ebimed.com
Date Prepared:	July, 18 2008
Trade/Proprietary Name:	BioDrive® Cannulated Screw System
Common/Usual Name:	Bone Screw
Classification Name:	Screw, Fixation, Bone (888.3040)
Device Classification:	II
Predicate Device:	Propeller Head Small Cannulated Screw System (K024086) Acid Etched Lag Screws (K070955) Synthes Cannulated Screws (K012945, K021932, K040765, K962011, K963172, K962823) DePuy SIJF Cannulated Screw System (K051296)
Non-Clinical Testing:	An engineering rationale has been prepared to demonstrate substantial equivalence to similar commercially available products. This engineering rationale can be found in **Section 18**.
Clinical Testing:	None provided as a basis for substantial equivalence.
Device Description:	The Biodrive® Cannulated Screw System consists of

cannulated screws of various diameters and lengths with four threaded configurations. The system includes 3 different size washers, the use of which are optional, as well as guide wire and complete instruments. They are made from made Titanium alloy (Ti-6AL-4V) in conformance with ASTM F136 standard. The Titanium screws are also available acid etched (Osseotite™).

Indications for Use:

- Fixation of fractures in long bones
- Fixation of small bones, including those in the foot, patella, ankle, wrist & elbow
- Arthrodesis of the foot, wrist and elbow
- Small and long bone osteotomies
- Fixation of pelvis and the illiosacral joint

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 5 2009

Biomet Trauma
% Ms. Christina Lakin, M.S.
Regulatory Consultant
100 Interpace Parkway
Parsippany, New Jersey 07054

Re: K082874
Trade/Device Name: BioDrive® Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: January 6, 2009
Received: January 7, 2009

Dear Ms. Lakin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082874

Device Name: BioDrive® Cannulated Screw System

Indications for Use: The BioDrive® Cannulated Screw System is indicated for the following:

- Fixation of fractures in long bones
- Fixation of small bones, including those in the foot, patella, ankle, wrist & elbow
- Arthrodesis of the foot, wrist and elbow
- Small and long bone osteotomies
- Fixation of pelvis and the illiosacral joint

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082874